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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/830,338 | 07/11/2001 | Johe Ikeda | 2001-0515A | 6935 |

513 7590 08/17/2004

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WASHINGTON, DC 20006-1021

EXAMINER

YU, MISOOK

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1642

DATE MAILED: 08/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

Advisory Action

Application No.

09/830,338

Applicant(s)

IKEDA ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 June 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 28 June 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s): enablement rejection of claims 2-4.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 2-4.

Claim(s) objected to: 13 and 17.

Claim(s) rejected: 1, 12, 14-16, 18 and 19.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

LARRY R. HELMS, PH.D.
PRIMARY EXAMINER

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Misook Yu, 8/12/04

Continuation of 5. does NOT place the application in condition for allowance because: Applicant argues that the rejection relies on the fact that the BIR motif lies within the epitopes the instantly claimed monoclonal antibody binds to as the alleged suggestion/motivation for generating antibodies to the BIR motif. However, there is no basis for this in the cited references. Nothing in the cited prior art teaches or suggests that the BIR motif contains epitopes, let alone, those adequate for generating monoclonal antibodies that specifically bind an epitope in amino acids 256-586 or 841- 1052 of NAIP. While the cited references teach that BIRmotif is biologically important for NAIP, they neither teach nor suggest that the BIR motif contains epitopes to which an antibody specifically binds. The cited references fail to suggest that the BIR motif contains epitopes that can be used to generate the claimed monoclonal antibodies. Thus, there is no suggestion that the BIR motif disclosed in Thompson and Roy is adequate for an epitope to which an antibody specifically binds. These arguments have been fully considered but found unpersuasive.

WO 97/26331 teaches (pages 6 and 7, 21-24 especially, page 22 line 7 from the bottom of the page) monoclonal NAIP antibodies, and also teach a protein identical to the instant SEQ ID NO:1.


The primary reference does not teach monoclonal antibody with the specific binding epitopes i.e. amino acids 256-586, or 841-1052 of NAIP.

However, Roy et al teach human NAIP belongs to IAP protein family that are important for regulation of cellular apoptosis, and that BIR motif of IAP protein family is important for biological function(s) of the protein family (note the Introduction and abstract), and Roy et al further teach that deletion in NAIP is detected with most severe form of spinal muscular atrophy (note the paragraph bridging pages 6914 to 6915).

Roy et al do not explicitly disclose where the biologically important BIR motif is located in the human NAIP.

However, US Pat. 6,511,828 specifically discloses that the biologically important BIR motif lies within the epitopes the instantly claimed monoclonal antibody binds to, namely amino acid 276-349 of instant SEQ ID NO:1 (human NAIP). That patent at Fig. 3A, last row, teaches amino acid 276-349 of instant SEQ ID NO:1 is the biologically important BIR motif as taught by the secondary reference of Roy et al. Thus, the epitopes 276-349 of instant SEQ ID NO:1 is equivalent to BIR motif. In other words, the two refer to the single entity.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make antibody that binds to biologically important epitopes as taught as BIR motif by Roy et al with a reasonable expectation of success. .



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